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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,573	03/22/2001	Hector F. DeLuca	1256-00721	9707

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EXAMINER

JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/815,573	Applicant(s) DELUCA ET AL.	
	Examiner Shaojia A Jiang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2003 and 24 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 23, 2003 has been entered.

This Office Action is a response to Applicant's request for continued examination (RCE) filed July 23, 2003, and amendment and response, filed July 23, 2003 and November 24, 2003 wherein claims 1-7 are cancelled and claims 8-14 are newly submitted. Currently, claims 8-14 are pending in this application.

Claims 8-14 are examined on the merits herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Art Unit: 1617

Applicant's amendment with respect to new claims 8-14 has been fully considered but is deemed to insert new matter into the claims since the specification as originally filed does not provide support for "a method of reducing the amount of phosphorus in cow manure, comprising replacing a 1 α -hydroxylated vitamin D compound for some or all of the inorganic phosphorus in a diet of a dairy cow" and "feeding said diet to said dairy cow". The specification as originally filed merely discloses that "It is yet another object of the present invention to provide a method of maintaining milk production in a dairy cow while at the same time minimizing the need for supplemental inorganic P and increasing utilization of phytate P in the cow's diet" (see page 5 of the specification).

The specification as originally filed does not provide support for "said feed contains 0% by weight of an inorganic phosphorus supplement". The specification as originally filed merely discloses that "the present invention provides a method of compounding feed a dairy cow, comprising the steps of providing a feed supplement for a dairy cow that contains about 0.3% by weight or less of an inorganic phosphorus supplement; incorporating with said feed supplement ..." (see page 5 of the specification).

Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that Applicant was in possession of the invention as it is now claimed. See *Vas-Cath Inc. v. Mahurkar*, 19 USPQ 2d 1111, CAFC 1991, see also *In re Winkhaus*, 188 USPQ 129, CCPA 1975.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "some" or all in claim 8 is a relative term which renders the instant claims indefinite. The recitation "some" is not defined in the claims and specification. Hence, one of ordinary skill in the art could not interpret the metes and bounds of the patent protection desired as to the recitation "some" of inorganic phosphorus in a diet in the claim. Thus, the claims are indefinite as to how much "some" of inorganic phosphorus in a diet.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-10 and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Deluca et al. (WO 96/24258, PTO-1449 submitted June 25, 2001).

DeLuca et al. discloses a method of improving utilization of phosphorus as to reducing or minimizing or eliminating dietary requirements of phosphorus in animals (abstract, page 3 lines 13-15) such as cattle or cow (see particularly page 10 line 10) comprising feeding with the instant 1α -hydroxylated vitamin D compound (see page 7-8 in particular) in the effective amounts within the instant claim (see page 10 line 20-22), may be in a form of top dressing (see page 9 line 3). See also abstract, page 5 line 30 to page 6 line 3, page 9 line 15-17, and claims 18-20.

Thus, the disclosure of DeLuca et al. anticipates claims 8-10 and 12-14.

Claims 1 and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by DeLuca et al. (4,338,312, of record).

DeLuca et al. discloses that a 1α -hydroxylated vitamin D such as 1α -hydroxy vitamin D₃, within instant claim, with low phosphorus is useful in a method for prophylactically treating dairy cattle for parturient paresis. See abstract, col.2 lines 54-65, col.3 Example, and claims 1 and 3. DeLuca's teaching is inherent in a method of maintaining milk production in a dairy cow herein. See *Ex parte Novitski*, 26 USPQ 2d 1389. Thus, DeLuca et al. anticipates the claimed invention.

Claims 1 and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by DeLuca et al. (4,110,446, of record).

DeLuca et al. discloses that a 1α -hydroxylated vitamin D such as $1\alpha,25$ -dihydroxyvitamin D₃, within instant claim, is useful in a method of treatment and prophylaxis for milk fever in dairy cattle. See abstract, col.2 lines 37-49, col.5 lines 10-

Art Unit: 1617

19, and claims 1 and 6. DeLuca's teaching is inherent in a method of maintaining milk production in a dairy cow herein. See *Ex parte Novitski*, 26 USPQ 2d 1389. Thus, DeLuca et al. anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeLuca et al. (4,338,312 and 4,110,446).

The same disclosure of DeLuca et al. have been discussed above in 102(b) rejections.

DeLuca et al. do not expressly disclose the effective amount of 1 α -hydroxylated vitamin D to be administered is 0.1 to 100 μ g/kg as a top dressing on the feed. DeLuca et al. do not expressly disclose that said feed contains 0% by weight of an inorganic phosphorus supplement

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to motivated to optimize the effective amount of 1 α -hydroxylated vitamin D to be administered to 0.1 to 100 μ g/kg as a top dressing on the feed.

One having ordinary skill in the art at the time the invention was made would have been motivated to optimize the effective amount of 1 α -hydroxylated vitamin D to be administered to 0.1 to 100 μ g/kg as a top dressing on the feed because the optimization of amounts of active agents to be administered in the form of top dressing on the feed is considered well within the skill of artisan, especially, considered well within conventional skills in food industry.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Applicant's arguments filed on with respect to all rejections of record in the previous Office Action have been considered but are moot in view of the new ground(s) of rejections above.

In view of the rejections to the pending claims set forth above, no claims are

allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is 571.272.0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

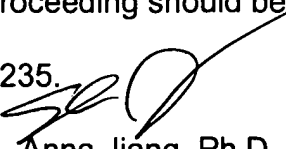
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on 571.272.0629. The

Art Unit: 1617

fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-

1235.



S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
February 12, 2004
